observed within two days after administration in Cohort 2, Cohort 3 is administered preparations having 30.0 μg total protein (0.1 ml ID). Each subject is followed for two days to assess local and systemic reactions.

[70] Subjects who were tested more than once during previous leishmanin standardization studies or healthy subjects receiving one administration of the lysate preparation serve to evaluate whether repeated skin-testing is sensitizing (n=60). This "Sensitizing Group" will receive a second dose of the lysate preparations and will be tested last.

[71] The controls are 0.1 ml saline and a 1:100 dilution of the microfluidized lysate preparation diluent comprising 0.001% Tween-80, 1% glycerol, 0.4% phenol diluted with 0.9% saline stored at 4 ± 2 °C. 0.1 ml of a microfluidized lysate preparation is injected intradermally into alcohol-cleansed volar surface of the forearm under the supervision of a physician who will have medication and equipment to treat anaphylaxis. The diameter of the induration, erythema, or both will be measured in millimeters at about 30 minutes after administration to detect immediate IgE hypersensitivity, and about 48 hours later to detect delayed type hypersensitivity by outlining the indurated border with a ballpoint pen and transferring to paper damped with 70% ethanol for permanent record. The largest diameter and its perpendicular diameter are measured and averaged. Alternatively, the Sokal method may be used. *See* Montenegro, J. (1926) Archives of Dermatology and Syphilology 13:187-194. The placement of each preparation and control for each subject are randomized and recorded. Skin test readers are unaware of the placements. Subjects are monitored closely.

[72] To the extent necessary to understand or complete the disclosure of the present invention, all publications, patents, and patent applications mentioned herein are expressly incorporated by reference therein to the same extent as though each were individually so incorporated.

[73] Having thus described exemplary embodiments of the present invention, it should be noted by those skilled in the art that the within disclosures are exemplary only and that various other alternatives, adaptations, and modifications may be made within the scope of the present invention. Accordingly, the present invention is not limited to the specific embodiments as illustrated herein, but is only limited by the following claims.